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Serial No. 09/801,486
Docket No. 20355-PA

REMARKS

The drawings were objected to because several reference characters have been used to designate more than one component. FIGS. 7-10, 12, 14 and 15 have been corrected herein to have each reference character designate only one component and to have the designations consistent through all of the figures. Enclosed herewith are FIGS. 7-10, 12, 14 and 15, in duplicate, with a Letter to the Official Draftsman showing the corrections in red and also with the formal drawings incorporating the corrections.

A review of the specification indicated that several reference characters were incorrectly designated. The specification has been amended herein to be consistent throughout and also to correspond with the corrected drawings.

Claims 1-17 have been cancelled herein without prejudice or disclaimer reserving the right to file a continuation application or take other steps to preserve the novelty of the invention recited therein.

Claims 14-17 were objected to for informalities. Claims 4, 6, 13-17 were rejected under 35 U.S.C. 112, second paragraph. Claims 1-12 were rejected under 35 U.S.C. 101. Claim 14 was rejected under 35 U.S.C. 102(b). Claims 1-17 were rejected under 35 U.S.C. 102(a) as being unpatentable over one or more cited references. These issues are now moot since claims 1-17 have been cancelled.

New claims 18-20 have been inserted herein. The informalities and bases of rejection stated in the Official Action have been considered in drafting of the new claims.

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The present invention is directed to a tracheostomy tube mounted in a neck plate which has integrally molded bands attached to the neck plate. A connector is provided to rapidly connect and disconnect the bands together so the neck plate and cannula can be comfortably fitted to the neck of the patient. The neck plate and the bands are formed from a viscoelastic polymer which is adapted to itself to the anatomy of the patient and, hence, is very comfortable and non-irritating. The device also has an adjustment means to provide for shortening or lengthening the band for increased patient comfort.

Wapner discloses a band for supporting tracheostomy tubes which has a neck plate. Two bands are provided which are not integrally molded to the neck plate. The two bands are formed from an outer layer of non-stretchable cotton and an inner layer of a sponge-like non-stretchable substance. The bands each have a Velcro strap which is threaded through an opening in the neck plate (column 2, lines 24-37). In assembly, the straps must be inserted in the openings, folded and secured. One of the bands is much shorter than the other and has an elastic webbed section which is connected by Velcro to the end of the other band. As noted on column 2, line 2 through column 3, line 3, the elastic band is stretchable but does not provide a great deal of stretch. The reference does not suggest nor disclose any viscoelastic polymer construction. In use the attendant must proceed through a series of steps (column 3, lines 14-22) which require time and may discomfort the patient. *Wapner* does not disclose or suggest a rapid connector means as claimed by the applicant.

Tuman discloses an endotracheal tube support device. This device is not for a tracheostomy tube for the patient's neck but secures a tube in the vicinity of the patient's nose or mouth (column 2, lines 45-47). This is further shown in FIG. 2. A strap is formed from a rayon/nylon material. The

reference does disclose a quick release connector. However, it is submitted that the device is not for a tracheostomy tube and there is no suggestion or disclosure that the device has application beyond the endotracheal use. There is no motivation for a person of ordinary skill in the art of tracheostomy to consider devices for endotracheal tubes and apply the devices to tracheostomy.

Belfer et al disclose a strapless respiratory facial mask which has a thermoplastic material around the edges. The elastomeric cushioning material is used for peripheral sealing (column 10, lines 39-40). There is no suggestion nor disclosure that the entire facial mask be formed from the elastomeric material. Further, it is submitted that persons of ordinary skill in the art of tracheostomy have no motivation to consider respiratory facial masks.

Lane discloses a helmet and face mask interface system which has an adjustment means to adjust a strap which holds the helmet to the mask. There is no suggestion or disclosure that the system be used with a tracheostomy tube. There is no motivation for persons of ordinary skill in tracheostomy to be aware of, or consider, the helmet and face mask of *Lane*.

The Examiner has cited and relied upon a number of references from diverse technologies which are unrelated to the present field of tracheostomy and which consequently offer no teachings of applicable merit to those of ordinary skill in the art of tracheostomy. There is no teaching or suggestion in the cited references of how the art would be applied to the field of tracheostomy. Rather, it is only coincidental that there are a few isolated features which resemble those recited in the present claims. However, the cited references are without the common purpose, benefits and advantages attained by the present invention. It is respectfully requested that the Examiner reconsider the applicability of these references to the present rejection, since these are not a part of,

or in any remote way related to, the field of the present invention, nor is there any teaching, suggestion or motivation apparent therein which would suggest that one of ordinary skill in the field of tracheostomy would look to these documents for teachings applicable to tracheostomy. The present invention and those references are, in fact, wholly unrelated in the determination of the scope and contents of the relevant prior art.

It is further submitted that not only is there no motivation to combine the cited references but even if combined, the resulting device would have a neck piece connected by straps with Velcro attachment to a fabric band. The neck piece would have a peripheral seal of elastomeric material. The neck piece would not be integral with the bands and would not be formed from a elastomeric material. In use, the straps would need to be threaded through the openings in the neck piece and the bands disposed around the neck of the patient. It would then have to be adjusted for the comfort of the patient. This would take time while working on a seriously ill patient. Even slight movement of the endotracheal tube in the incision in the patient's throat is painful. The cited references, or a device resulting from the combination thereof, due to their very nature, would cause discomfort, if not pain, to the patient. The present invention is very simple to install, taking much less time, and the material of construction significantly reduces movement of the endotracheal tube. The present invention provides significant improvement to the health and comfort of the patient.

In addition, although *Wapner* has been known since 1982 and the viscoelastic polymer AKTON[®] identified by the applicant (page 8, line 3) has been commercially available since 1982 (as shown by the enclosed U.S. Trademark Registration No. 1,289,020) no one has combined these in any manner. Thus, contrary to the conclusion of the Examiner, there is no evidence that it was

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obvious to one of ordinary skill in the art to make the bands, and the neck piece, of the viscoelastic polymer or to form the bands integrally with the neck piece.

Claims 18-20 are currently pending in the application. The newly added claims replace original claims 1-17 and more specifically recite the fasteners and benefits of the present invention that are novel. More particularly, the claims recite the neck piece integrally formed with the bands and made from a viscoelastic polymer.

In view of the recitations in each of the independent claims as now recited by the present Amendment, and the absence of such or teachings thereto in the prior art, the Examiner is respectfully requested to reconsider the rejection and pass this application to allowance. No new matter has been introduced in the present Amendment.

It appears that all matters have been addressed satisfactorily, and that the case is now in condition for a complete allowance; and the same is respectfully urged.

However, if the Examiner has any comments or questions, or has any suggestions as per MPEP 707.07 (d) and (j), for putting the case in condition for final allowance, she is respectfully

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urged to contact the undersigned attorney-of-record at the telephone number below, so that an expeditious resolution may be effected and the case passed to issue promptly.

Respectfully submitted,

Date

Robert M. Gamson
Reg. No. 32,986
Attorney for Applicant

CERTIFICATE OF TRANSMITTAL

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail in an envelope addressed to: Commissioner of Patents and Trademarks, P.O. Box 2327, Arlington, VA 22202.

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